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10/561,725	03/08/2007	Andreas Pein	00599P0010US	8226

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GUDRUN E. HUCKETT DRAUDT
SCHUBERTSTR. 15A
WUPPERTAL, 42289
GERMANY

EXAMINER

MILES, JONATHAN WADE

ART UNIT	PAPER NUMBER
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3731

MAIL DATE	DELIVERY MODE
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03/12/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/561,725	Applicant(s) PEIN, ANDREAS	
	Examiner JONATHAN W. MILES	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 January 2010 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Response to Amendment

This office action is in response to the amendment filed on January 7, 2010. Claims 1-7 remain canceled. Claims 8-13 have been amended, and claim 14 has been added. Claims 8-14 are pending and addressed below.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the structure of the suction pipe sheathing the pressure tubule in the manipulable operating device in claim 1 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will

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be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 8 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Regarding claim 8, the annular membrane having an inside periphery attached to the cylinder wall and an outside periphery attached to the piston is not supported by the specification or the drawings, and furthermore, appears to be impossible to implement. The inside periphery would need to be attached to the piston, because the piston is inside the cylinder wall. In the specification, the applicant does disclose the membrane extending between the cylinder casing and the piston, but does not specify which portion of the membrane is attached the piston and which portion of the membrane is attached to the cylinder casing. Further inspection of Fig. 2 seems to indicate that the outer periphery (according to the examiner's interpretation) is actually attached to the cylinder wall, and the inner periphery is attached to the piston. Thus there is no support for the language of claim 1.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 8, 11, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoder et al. (US 5871462) in view of McDonnell et al. (US 591184). Yoder et al. is cited in the previous action.

Regarding claims 8 and 14, Yoder et al. discloses a water jet apparatus for severing a biological structure with a jet of severing liquid comprising water (column 3, line 64), the water jet apparatus comprising a storage container for the severing liquid (Fig. 1, [30]), a piston-cylinder unit comprising a cylinder (Fig. 2, [26]) formed in a cylinder casing (Fig. 1, [24]) and the cylinder having a wall and a bottom (see Fig. 2), a piston received in the cylinder casing for reciprocal motion of the piston in the cylinder with space remaining adjacent the bottom of the cylinder (Fig. 2, [60]), the space functioning as a pressure space upon downstroke of the piston and as a suction space upon upstroke of the piston (Fig. 3, [94]; the direction of a “downstroke”

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and an “upstroke” is relative to the orientation of the cylinder; likewise, the “bottom” of the cylinder is relative, completely dependent on the orientation of the cylinder), and an annular membrane having an inside periphery attached to the cylinder wall at a position in an upper zone of the piston-cylinder unit and an outside periphery attached to the piston at a position in the upper zone of the piston-cylinder unit (Fig. 3, [86]; wherein the outside periphery is attached to the piston via the cylinder), the upper zone being defined by an annular space above the suction-pressure space (Fig. 2, [64]), the membrane sealing interior of the piston-cylinder unit below the membrane from exposure to the ambient outside the piston-cylinder unit and the membrane being dimensioned so as to allow reciprocation of the cylinder and the annular space being dimensioned so as to allow movement of the membrane therein as the piston reciprocates and the accommodate the membrane when the piston is at rest at end of a downstroke (column 7, lines 56-63; see Fig. 2), a manipulable operating device including a pressure tubule terminating in the jet (Fig. 1, [40]), a suction line for conducting the severing liquid from the storage container to the suction-pressure space in the cylinder (Fig. 1, [32]), a pressure line for conducting the severing liquid from the suction-pressure space in the cylinder to the operating device (Fig. 1, [36]), and a coupling for attaching the eccentric drive to and detaching the eccentric drive from the piston (Fig. 2, [62]), the piston-cylinder unit together with the suction line, the pressure line and the operating device constituting a sub-assembly, wherein the suction line is attachable to and detachable from the storage container and the cylinder casing by means of a first and a second coupling and the pressure line is attachable and detachable from the manipulable operating device by a third coupling (see Fig. 1; column 2, lines 59-61); but does not disclose a manipulable operating device including an internal pressure tubule terminating in the jet and a

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suction pipe sheathing the pressure tubule or wherein the suction pipe of the manipulable operating device is connected via an exhaust line to a pump.

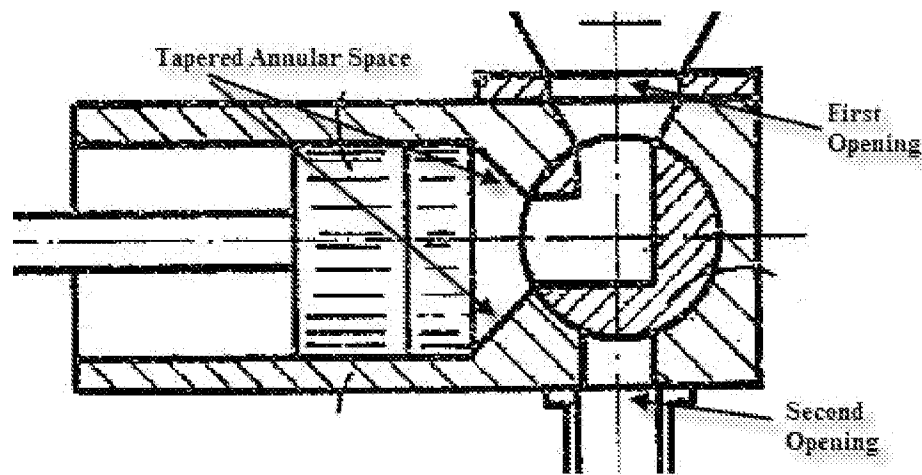
However, McDonnell et al. discloses a manipulable operating device (Fig. 1, [10]) including an internal pressure tubule terminating in the jet (Fig. 7, [36]) and a suction pipe sheathing the pressure tubule (Fig. 7, [100]), and wherein the suction pipe (Fig. 7, [66]) of the manipulable operating device is connected via an exhaust line to a pump (column 6, lines 56-57).

It would have been obvious to combine the manipulable operating device of McDonnell et al. with the water jet apparatus of Yoder et al. because it allows for suction and jetting of water. The motivation for the modification would have been to remove excess fluid and emulsified tissue from the surgical site (McDonnell et al., column 6, lines 67-69).

Regarding claim 11, Yoder et al. in view of McDonnell discloses the water jet apparatus according to claim 8, further comprising a protruding sealing lip formed on the cylinder (Fig. 2, [70]).

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yoder et al. (US 5871462) in view of McDonnell et al. (US 591184) as applied to claim 8 above, and further in view of Gernlein (US 4234107). Gernlein is cited in the previous action.

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**Image 1 from Gernlein Fig. 2**

Regarding Claim 9, Yoder et al. in view of McDonnell et al. discloses the water jet apparatus according to claim 8, but does not disclose wherein at least a lowermost portion of the annular space tapers inwardly in a downward direction toward the suction-pressure space, the taper being formed by a frustoconical portion of the cylinder wall.

However, Gernlein discloses a fluid pump wherein the lowermost portion of the annular space tapers inwardly in a downward direction toward the suction-pressure space, the taper being formed by a frustoconical portion of the cylinder wall (see Image 1 above).

It would have been obvious to combine the tapered shape of Gernlein with the water jet apparatus of claim 8 because the shape prevents the piston from being extended any further. The motivation for the modification would have been to create a stop for the piston prior to extending all the way until it reaches the lowermost portion of the annular space.

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Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yoder et al. (US 5871462) in view of McDonnell et al. (US 591184) as applied to claim 8 above, and further in view of Allen (US 3622251). Allen is cited in the previous action.

Regarding Claim 10, Yoder et al. discloses the water jet apparatus according to claim 8, but does not disclose the cylinder casing and the piston being constituted of plastic.

However, Allen discloses a cylinder casing and piston being constituted of plastic (column 2, lines 69-71).

It would have been obvious to combine the plastic material of Allen with the piston and casing of claim 1 because plastic is more lightweight (Allen, column 3, line 43). The motivation for the modification would be to make the apparatus more mobile.

Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoder et al. (US 5871462) in view of McDonnell et al. (US 591184) as applied to claim 8 above, and further in view of Rogers (US 4551146). Rogers is cited in the previous action.

Regarding Claim 12, Yoder et al. in view of McDonnell et al. discloses the water jet apparatus according to claim 8, further comprising: a connecting device installed in the cylinder for connected the pressure tube to the suction-pressure space (see Fig. 3 where the pressure tube [36] connects to the cylinder [26] and a first opening through the cylinder casing (Fig. 3, [112]), and a connecting device comprising a pressure sleeve press fit into the first opening through the cylinder casing for effecting communication of the pressure line with the suction-pressure space (column 4, lines 41-45) but does not disclose the connecting device comprising a pressure tubule concentrically received in the pressure sleeve and having external ribs spaced from an interior

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wall of the pressure sleeve by a distance corresponding to thickness of a wall of the pressure line, the wall of the pressure line at an end portion of the pressure line being gripped between the ribs of the pressure tubule and the interior wall of the sleeve.

However Rogers discloses a connecting device comprising a pressure sleeve (Fig. 3, [30]), a pressure tubule concentrically received in the pressure sleeve (Fig. 3, [18]) and having external ribs spaced from an interior wall of the pressure sleeve by a distance corresponding to thickness of a wall of the pressure line (Fig. 3, [20]), the wall of the pressure line at an end portion of the pressure line being gripped between the ribs of the pressure tubule and the interior wall of the sleeve (column 3, lines 41-43; see Fig. 4).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the pressure sleeve and the pressure tubule of Rogers with the water jet apparatus of Yoder et al. because it minimizes the possibility of a bacteria invasion (Rogers, column 1, lines 59-60). The motivation for the modification would have been to disinfect the connection during its use (Rogers, column 1, lines 12-13).

With regard the statement of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over Yoder et al. in view of McDonnell et al. in further view of Rogers which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Regarding claim 13, Yoder et al. in view of McDonnell, in further view of Rogers discloses the water jet apparatus according to claim 12, further comprising a second opening through the cylinder casing (Yoder et al., see Fig. 1 where the suction line [32] connects to the

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cylinder [26], see in more detail in Fig. 3), the second opening effecting communication of the suction line with the suction-pressure space (Yoder et al., column 7, lines 39-41), but does not disclose the first and second openings being radially oriented and diametrically opposed with respect to the cylinder whereby the connecting device is installable in the first opening by initial insertion thereof through the second opening.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to place the first and second openings radially oriented and diametrically opposed with respect to the cylinder, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

Response to Arguments

Applicant's arguments with respect to claims 8-13 have been considered but are moot in view of the new ground(s) of rejection. Many of the arguments addressing the art used by the examiner have been addressed in the rejection; however, the applicant insists that the pump of Yoder et al. is not a piston pump, such as the pump claimed.

The examiner would like to point out that Yoder et al. clearly refers to element 60 as a "piston rod," and clearly calls the device a "piston pump" on multiple occasions, including column 4, line 22. Furthermore, as long as the device contains a piston and performs a pumping action, the device may be classified as a piston pump. The applicant must further structurally separate the claimed pump from the pump discloses in Yoder et al.

Conclusion

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JONATHAN W. MILES whose telephone number is (571)270-7777. The examiner can normally be reached on Monday-Thursday 7:30 am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571)272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jwm

/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
3/11/10